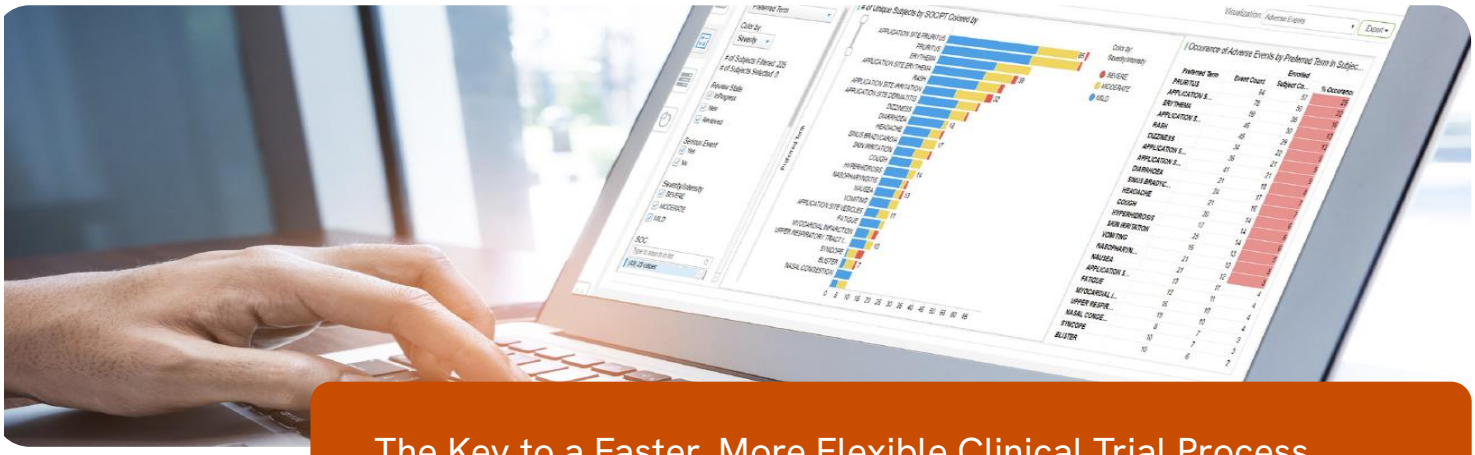
WHITE PAPER



The Key to a Faster, More Flexible Clinical Trial Process

How a single, integrated data analytics and visualization platform, supported by an experienced partner, can help you move your investigational product to market more quickly.

Introduction

Clinical development teams are under enormous pressure.

Pressure from financial stakeholders, who expect a timely return on their investment; pressure from regulators, who are closely scrutinizing the biopharma industry as it explores new therapeutic platforms; most of all, pressure from patients and their families, who are waiting for much-needed cures and life-enhancing treatments.

As they navigate the lengthy and challenging clinical trial process, study teams need to alchemize these pressures into opportunities for greater collaboration, risk management, and quality. For example, many trial sponsors are responding to increased regulatory scrutiny by moving their medical monitoring activities out of CROs and into their own internal process, which means improved data quality and better cost control. But adapting to these changes while maintaining speed, safety, and data integrity is a challenge that companies of different sizes often experience in unique ways.

Small companies may be struggling with how to begin.

- Under regulatory pressure, many sponsors are looking for ways to closely monitor the data arriving from study sites. This requires robust analytical solutions that may be difficult for lean startups to identify, install and operationalize without an IT team leading the way.
- Manually building safety and efficacy plots and other data visualizations using off-the-shelf solutions like Excel takes enormous time and effort, impeding critical and time-sensitive decisions.

To master the clinical trial process, you need to master clinical trial data. But you don't need to do it alone.

Whether you're a startup or well-established company, we'll help you answer three questions that are essential to your success:

1. How are data-related challenges stalling your clinical trials?
2. What do highly productive study teams know about managing clinical data?
3. How can you remove data bottlenecks and reach better trial outcomes, sooner?

This paper is the beginning of your transition to a simpler, faster, more agile clinical trial experience. When you're ready for your next step, so are we.

Large and mid-sized companies may be struggling with how to keep moving.

- More mature companies have access to established IT resources, but mobilizing those resources quickly and effectively is not easy.
- These companies have sophisticated tools, but they lack flexibility. They may struggle to operationalize an enterprise BI platform within the narrow context of an individual study or in response to an executive request for specific visualizations.

Adapting to change while maintaining speed, safety, and data integrity is a challenge that companies of different sizes often experience in unique ways.

Let's examine these and other common challenges, with the aim of better understanding how clinical development teams can maneuver around potential roadblocks and turn the promise of their investigational product (IP) into a commercial and therapeutic success story.

How Are Data-Related Challenges Stalling Your Clinical Trial?

If You're a Startup, Using Data to Track Safety and Satisfy Stakeholders and Regulators May Be a Challenge.

In many ways, small drug developers who launch a clinical trial are in a coveted position. Few manage to get that far, and those who do have overcome the initial challenges of bringing IP to market: they've persuaded investors to fund their research, and regulators to approve their investigation.

In other ways, these companies are in a very difficult position. Only about 14% of IP candidates that enter the clinical trial process will exit as an approved and commercially available therapy.[1] The rest succumb to one of the many pitfalls facing nascent IP. These pitfalls very often have to do with data. Maybe it doesn't arrive quickly enough from study sites. Maybe it arrives in different forms, which costs valuable time. Maybe its quality is poor, or it's incomplete. Any one of these barriers can seriously impair progress, especially for lean teams with limited resources.

Sometimes, small companies turn to familiar products like Excel for help. That can work as long as you're still in an early phase, with just a few subjects to juggle. As your trial progresses, though, building visualizations from rapidly multiplying lines of data becomes a gargantuan task. It's a bit like building a car from individual engine components; not impossible, but you'll need to invest a lot of time, patience, and know-how before you've got a road-worthy vehicle. Far better to begin with a flexible solution that's purpose-built for the life sciences—in other words, a car designed with your needs in mind, ready to drive off the lot and get you where you need to be faster and far more safely.

If You're a Large Or Mid-Sized Company, Maintaining Speed And Flexibility May Be a Challenge.

Large and mid-sized drug developers typically have an internal IT task force and an established BI infrastructure to rely on, which is a perceived advantage over smaller, leaner startups. That advantage comes at a price, though. While these companies may be rich in technological resources, they're often slow to operationalize those resources according to the needs of a particular clinical development team. Keeping data clean, complete and submission-ready is the priority; adapting visualizations to suit the unique needs of a particular trial is not. This impairs the ability of certain study teams to see into their data in a way that's meaningful to them.

Excel can work as long as you're still in an early phase, with just a few subjects to juggle. As your trial progresses, though, building visualizations from rapidly multiplying lines of data becomes a gargantuan task.

To deal with these challenges, clinical development teams might assemble a daisy-chain of point solutions to approximate an end-to-end workflow—one solution that provisions source data, another that translates it into visualizations, and so on. This is an improvement on the limited functionality of Excel, but it introduces its own risks (each "handshake" between different systems is an opportunity for compromised integrity) and its own operational challenges (teams must compete for the internal resources required to set up these sophisticated solutions).

THE "BEFORE" PICTURE

Snapshot of a Startup Slowed By A LABOR-INTENSIVE DATA REVIEW PROCESS	*Snapshot of a Mature Company* STRUGGLING TO OPERATIONALIZE THEIR TOOLS
THE OBJECTIVE Analyze the safety and efficacy of the IP. POTENTIAL ROADBLOCKS • It's difficult to monitor the integrity of source data arriving from CROs using a one-size-fits-all consumer product like Excel. • Safety signals, buried in hundreds of lines of inert data, are easy to miss. • Clinical trial teams are spending too much time manually importing data, cleaning it, and building safety and efficacy plots, leaving too little time for meaningful investigation.	THE OBJECTIVE Continuously review clinical data and act quickly on operational analytics POTENTIAL ROADBLOCKS • The company's growing portfolio is stretching the capabilities of its existing analysis and reporting tools. • A fragmented tech stack is impairing the study team's ability to accurately review data and make meaningful protocol amendments. • Data scientists and biostaticians are investing significant time in preparing data for medical review by a physician, which is slowing study progress and potentially impacting safety.

What Do Highly Productive Study Teams Know About Managing Clinical Data?

When Startups Automate Data-Related Tasks, They Free Clinical Trial Teams For Important Early Research.

The key to untethering a study team from the manual and arduous process that slows it down? Automation. An intelligent clinical analysis platform can relieve many of the manual data aggregation and presentation tasks that bog down study teams, freeing them for more high-value analysis and interpretation.

An automated solution also means that stakeholders are empowered to access safety and efficacy plots and other key details through self-service dashboards, designed to pull in the latest data and present it in highly visual and intuitive ways (no data science degree required).

More importantly, intelligent automation means that the clinical development team can interact with data as soon as it's collected from study sites. This makes it easy to continuously monitor incoming data and clean it when necessary, and it provides an opportunity to flag and correct a protocol violation before it threatens the study's progress. Study managers, biostatisticians, medical monitors and others can spend their time exploring and analyzing an array of dynamic, purpose-built data visualizations, rather than reworking outdated reports and wrangling data into safety and efficacy plots.

Nimble Solutions Help More Mature Companies Accelerate Instream Analysis.

More trial subjects. More trial sites. More money flowing in, which means more pressure bearing down. To maneuver through this world of "more, more, more," highly productive study teams rely on fast and flexible tools and experienced external partners to help them manage the needs of their particular study. In environments where one clinical development team might compete with many others for the same IT resources, having this one-two punch of operational flexibility and experienced partnership makes a measurable difference.

THE "AFTER" PICTURE

Snapshot of a Startup That **MOVES FAST AND PROTECTS DATA INTEGRITY.**	*Snapshot of a Mature Company That* TURNS COMPLEXITY INTO DEXTERITY AND ACTION.
By automating their data provisioning and visualization activities, clinical development teams in small-scale startups are able to: • Generate dynamic safety and efficacy plots and share them with stakeholders, accelerating decisions and driving action. • Go straight to meaningful visuals that make safety signals easy to detect and investigate, saving hundreds of hours and greatly reducing overall risks. • Flexibly adapt to shifting protocols and other operational changes, without compromising data quality, cleanliness or completeness.	With a flexible, centralized data analytics and visualization solution to rely on, study teams are able to: • Generate dynamic safety and efficacy plots and share them with stakeholders, accelerating decisions and driving action. • Integrate data from multiple sources for meaningful, layered visualizations tailored for their therapeutic area. • Free more time for meaningful work, such as transferring their knowledge and experience to adjoining teams who are in the early stages of trial development.

How Can You Remove Data Bottlenecks and Reach Better Trial Outcomes, Sooner?

To transition from traditional data handling practices to a holistic approach built for speed and agility, clinical trial teams need two interdependent pieces in place:

A SINGLE, INTEGRATED TRIAL ANALYTICS AND VISUALIZATION PLATFORM

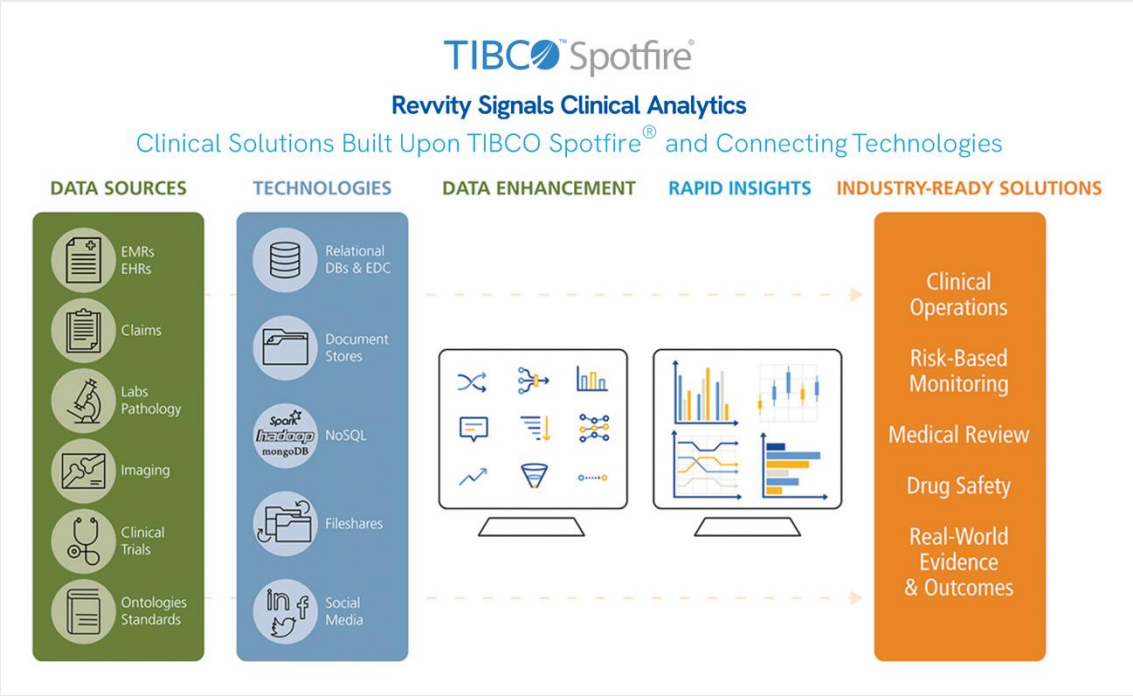
+

A CLINICAL ANALYTICS PARTNER WITH DEEP DOMAIN EXPERTISE

Why a Single, Integrated Trial Analytics Platform?

In order to serve the many roles that are active across the R&D lifecycle, companies might rely on a string of standalone point solutions from multiple vendors. This approach requires data to "jump" from one vendor's solution to the next as a trial progresses, which slows data analysis and introduces opportunities for error or overlooked insights. Disparate point solutions can also fracture the study team into silos, reducing visibility across the trial lifecycle and making decisive action difficult.

With a single, integrated enterprise trial analytics platform supporting your key clinical data use cases, many of these challenges disappear. That's our commitment at Revvity. Our platform, the only one on the market powered by global analytics leader TIBCO Spotfire®, is designed to facilitate translational and clinical use cases via a portfolio of purpose-built solutions. Each solution is designed to integrate smoothly together and ladder up to the centralized platform, resolving the "gap issue" that can compromise data as it jumps between different vendors' tools. As a result, biostaticians, medical monitors, CROs, sponsors, and other stakeholders across the clinical study lifecycle function as a single team moving towards a shared purpose.

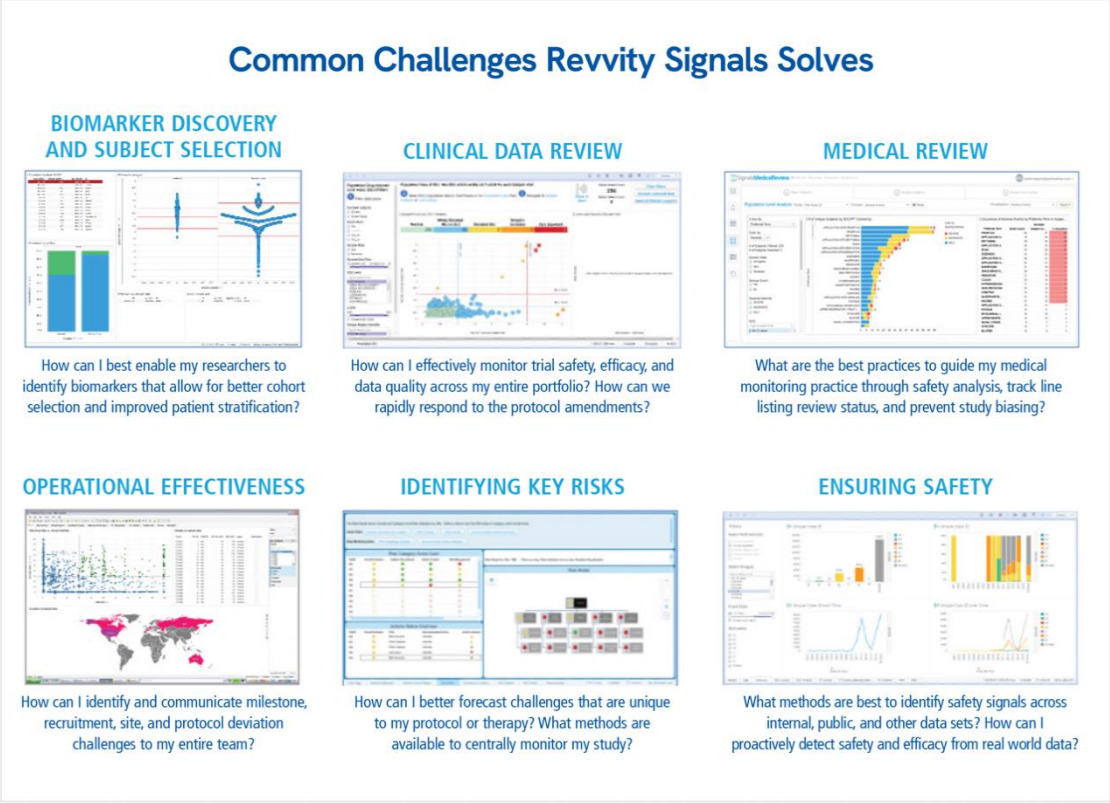


With our TIBCO Spotfire® platform powering your clinical trial, you and your team can:

- Manage your entire portfolio of clinical trials with solutions built to power everything from discovery through trial safety and efficacy analysis, clinical operations, and beyond.
- Harmonize real-time data from multiple sources including Clinical Trial Management Systems, Electronic Data Capture Systems, SAS, SDD and SAS/SHARE, and more.
- Get the answers you need, in the format you need them. The platform is fast and flexible, giving study teams guided, persona-based access to centralized trial data in real time.
- Move smoothly through your R&D lifecycle with integrated solutions powered by the same platform. Go beyond traditional data storage, management, and reporting techniques with a suite of linked solutions designed to work fluidly together, supporting key functions in a way that resonates with each team's unique needs.

Why A Partner With Extensive Domain Expertise?

Life Sciences R&D is Revvity's core focus. From years of experience on the front lines of pharmaceutical IP development, we've cultivated a deep understanding of this industry and its challenges and opportunities. That's how we've turned the world's most complete analytics solution into a powerful tool for clinical trial teams.



On its own, TIBCO Spotfire® is a robust option for any industry with advanced analytics needs; with our expertise behind it, it becomes an essential part of the pharmaceutical R&D workflow, helping to accelerate decisions and drive innovation from concept through trial completion and regulatory approval.

Our experts will partner with your team to:

Solve small problems before they become big ones. We've seen it all, and we know what's required to avoid losing valuable time and money on development and validation efforts. With our expertise on your side, you'll move faster than ever, with fewer headaches to slow you down and better outcomes to celebrate at the finish line.

Continuously adapt your solutions to suit your trial's shifting needs. We live and breathe clinical trials, and we know the TIBCO Spotfire® platform inside and out. This means that we can work alongside you to tailor your analysis and visualization solutions according to your unique needs, and we can scale our solutions alongside your study so that you'll never outgrow your technology.

Navigate the regulatory landscape with greater ease. We understand the complex regulatory approval process. Our experience, combined with a data solution that offers a 360-degree view for all CDISC domains, a full audit trail, and complete vendor oversight, means that you'll be submission-ready sooner, with a diminished risk of rejection or market withdrawal.

The bottom line: whatever your particular challenges are or therapeutic areas you focus on, our industry-trained professional services team can help. Our exclusive partnership with TIBCO Spotfire® means that we have the tailored data solutions you need to ensure end-to-end safety, efficacy and data integrity; our domain experience means that you'll be working alongside a team that speaks your language and knows what you're up against.

CASE STUDY: Revvity Signals + TIBCO Spotfire® in action

FROM FIRST PATIENT TO DATA VISUALIZATIONS IN UNDER FOUR DAYS

As you know, it takes months to move from pre-clinical to first patient first dose for a new trial. When one of their existing biologics showed promise as a treatment for COVID-19, a leading biotech company asked Revvity for the near-impossible: "Can you help us move from preclinical to first dose in days, not months?"

One major complication to accelerating their COVID-19 studies was the need to anticipate the protocol data coming in and design the most effective visualizations for the monitoring team. We got to work.

Over seventy-two hours, our domain experts leveraged TIBCO Spotfire® to tailor effective safety and efficacy visualizations for the monitoring team based on the protocol data arriving from their study sites. In under four days, the clinical data review process began.

For speed, flexibility and quality, turn to the experts who understand your domain and can build solutions that support your timeline and therapeutic area.

Do you have an upcoming trial where you would like to go from first patient first dose to safety and efficacy data analysis faster than usual? Are you held up because of the difficulty in figuring out how to structure the analysis and visualizations based on the types and sources of clinical data you will capture? Do you need a single clinical solution that answers all of your clinical challenges?

Contact us to learn how we can introduce more speed and agility into your clinical development analytics needs.

Reference

1. https://www.centerwatch.com/articles/12702-new-mit-study- puts-clinical-research-success-rate-at-14-percent

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